K112116

510(K) SUMMARY

OCT 4 2011

AS REQUIRED BY SECTION 21 CFR 807.92(c)

Amperor Electronics (SZ) Co., Ltd.
Digital Clinical Thermometer Model V901US

1. SUBMITTED BY, CONTACT PERSON AND DATE OF THIS SUMMARY:

A. Company Name: Amperor Electronics (SZ) Co., Ltd.

Address: 8, Sarpotau Building, Ku-Su Village, Shi-Shian Town, Baoan County, Shenzhen, Guang dong P.R. China

B. Contact Person

Amperor Electronics : Steel Chen, Director, Safety and Regulatory

Kaz USA, Inc: Raj Kasbekar, Global Vice-President, Regulatory Affairs

C. Date of Preparation of this Summary:

September 12, 2011

2. DEVICE NAME:

Table 1: Device Names

	Device
Proprietary Name	**V901US**
Common/Usual Name	**Digital Clinical Thermometer**
Classification Name	**Clinical electronic thermometer**

3. DEVICE CLASSIFICATION:

Digital Clinical Thermometer V901US (21CFR 880.2910, Product Code FLL) has been classified under section 510 of the Act as Class II (Clinical Electronic Thermometer).

4. INTENDED USE / INDICATIONS FOR USE:

The Digital Thermometer Model V901US is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm. The device is intended for the adult and pediatric population.

The Digital Thermometer Model V901US is a hand- held, non-sterile, reusable clinical thermometer intended for the determination of human temperature in either predictive (Instant) mode (10-seconds in oral, rectal mode and under the arm mode-predicative temperature, or standard mode (actual determination of temperature).

5. SUBSTANIAL EQUIVALENCE:

The digital thermometer model V901US is substantially equivalent to the predicate device V9XX (K082266) made by Amperor electronics (SZ) Co., Ltd., for the following reasons:

1) It has the same intended use/indication for use as the predicate.
2) It has the same operating principle and technological characteristics as the predicate.
3) The digital thermometer model V901US has some minor changes from the predicate device that include speed of temperature determination and display, change in battery type, display graphics, audible beep intensity and power down time. These changes have been verified and validated (as part of performance testing) and are included as part of this submission. A summary of these verification and validation activities is attached. These changes raise no new issues of safety and effectiveness.

The changes (minor) to the new device include:

1. The speed of temperature determination and display has increased.
2. Change in battery type from CR1225(3V) to LR41(1.5V).
3. The power down time has been changed from 90s to 10min.
4. The intensity of the three color backlight is reduced.
5. The indication icon for less than 32C has been changed from "L" to"Lo".
6. The indication icon for more than 42.9C has been changed from "H" to"Hi".

7. "Valid complete" beeps have been changed from 5 Beeps to 10 Beeps.
8. Fever alert point has been changed from 38.3C to 37.8C.
9. Changed the appearance of housing.

Design Control Activities Summary				
Device Modification	**Change in Risk**	**Verification Activity**	**Acceptance Criteria**	**Results of Verification**
Device Related Changes				
Changes to device hardware, software or sensors.				
Changes to device hardware.				
Battery change from type:CR1225(unrechargeable)3V to type:LR41(unrechargeable)1.5V	No change in risk profile	The verification activity for the change in battery includes confirmation that the unit can go into the operating mode and factory mode and carry out its normal functions. Start the unit and hold the start button for 3 seconds. The unit should enter the factory mode. Take a few readings in this mode. Shut the unit off and start it again. This will put the unit in the operating mode. Take a few readings in this mode.	The Unit should go into the factory mode and operating mode and function as expected.	PASS. Traceable to V901US Design Verification Tests 1 thru 28.
Backlight change from three color: green,orange and red to do not have backlight.	No change in risk profile	Start the unit. Ensure that the unit does not have backlight in normal and elevated temperature situations.	Verify by observation that unit does not have backlight.	PASS. Traceable to V901US Design Verification Test 11.

The indication icon for less than 32°C has been changed from "L" to"Lo"	No change in risk profile	For the normal operating mode, the software shall signal the user with no language-specific words other than Err, HI and Lo. These messages are widely understood and have precedent for successful acceptance in other internationally distributed products.	Verify by observation that the "Lo" indicator comes up for temperature below 32.0°C or 90°F	PASS. Traceable to V901US Design Verification Test 12.
The indication icon for more than 42.9°C has been changed from "H" to"Hi"	No change in risk profile	For the normal operating mode, the software shall signal the user with no language-specific words other than Err, HI and Lo.These messages are widely understood and have precedent for successful acceptance in other internationally distributed products.	Verify by observation that the "Hi" indicator comes up for temperature above 42.9°C or 109.9°F	PASS. Traceable to V901US Design Verification Test 12.
Changes to device software.				
Measurement time change from 8 seconds to 10 seconds.	No change in risk profile	Start the unit. Take a reading using a simulated waterbath. Record the time required to take a reading. The average time shall be less than 10 seconds.	The average measurement time shall be less than 10 seconds.	PASS. Traceable to V901US Design Verification Test 1.

The amount of beeps after a measurement is complete has changed from 5 beeps to 10 beeps.	No change in risk profile	Start the unit. Take a reading using a simulated water-bath. Verify that the number of beeps to indicate end of a measurement is 10 .	Verify by observation that the number of beeps after a measurement is complete is 10.	Pass. Traceable to V901US Design Verification Tests 2 and 26.
The Fever alert point has been changed from 38.3°C/100.9 to 37.8°C/100.0.	No change in risk profile	Start the unit. Set the water bath temperature to above 100 deg F. Take a reading in the water-bath. Verify that the fever alert beeps sound.	Verify by observation that the number of beeps for fever is activated.	PASS. Traceable to V901US Design Verification Test 26.
The power down time has been changed from 90s to 10min.	No change in risk profile	Start the unit. Keep it in the on state for over 10 minutes. Software control unit should turns itself off automatically if there is no action taken for 10 minutes (± 1 minute).	Verify that Auto power turns the unit off in 10 ± 1 minutes when no action is taken.	Pass. Traceable to V901US Design Verification Test 3.
A separate Factory mode was added that can be triggered only by inputting a password.	In the older version, the factory mode was triggered without any user input. This was changed such that a user has to intentionally put in a password to enable the factory mode. This was done to reduce the risk related to any inaccurate measurements during normal clinical use. This improved the risk	1. After starting the unit, press and hold the ON switch (power key) for more than 3 seconds. The signal "- - -" will appear. Then key in a right one digit password, by pressing the same ON switch, which will put the unit into the factory mode. 2. Verify accuracy of the product in a water bath.	1. Verify that the unit goes into the factory mode. 2.The product should have the following accuracy in water-bath mode: ±0.2 °F 98.0°F-102.0°F ±0.3°F 96.4°F-97.9°F, 102.1°F-106.0°F ±0.5 °F <96.4°F or >106°F	PASS. Traceable to V901US Design Verification Tests 1 thru 28.

	profile of the thermometer by eliminating any inaccurate temperature measurements.			

Changes to device sensors.				
NONE				
Manufacturing Process Changes				
NONE				
Vendor Changes				
NONE				
Material Changes in Outer Casing of Device				
There was no change to any patient contacting material. The probe cover is the only part that comes in contact with the patient or end user. Biocompatibility Testing for the probe cover was addressed in 510(K) K082266 of predicate device.				
Labeling Changes				
Changes done may have been to clarify or further elaborate existing language only. Legal entity and format only.				

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Amperor Electronics (SZ) Company, Limited
% Mr. Raj Kasbekar
Regulatory Affairs
Kaz Incorporated
250 Turnpike Road
Southborough, Massachusetts 01772

OCT - 4 2011

Re: K112116
Trade/Device Name: Digital Clinical Thermometer Model V901US
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 13, 2011
Received: September 14, 2011

Dear Mr. Kasbekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

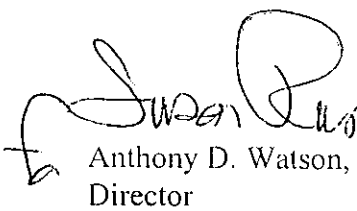
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

Intended Use/Indications for Use Statement

510(k) Number (if known): K112116

Device Name: Digital Clinical Thermometer Model V901US

Intended Use/Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/30/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Date: 2010-10-14
Revision: 1.1

510(k) Number: K112116